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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/000,004 | 05/02/2001 | Photini-Effie Tsilibary | 600.314USWO | 4637 |

23552 7590 08/07/2003

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EXAMINER

SAUNDERS, DAVID A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1644

DATE MAILED: 08/07/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

000,004

Applicant

TSILIBARY et al

Examiner

SANDER

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

P riod for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 4/18/03
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disp sition of Claims

- ☒ Claim(s) 31-42, 44-51, 53-56 is/are pending in the application.
- Of the above claim(s) 35-42, 49-51, 53-56 is/are withdrawn from consideration.
- ☒ Claim(s) 31-34, 44-47 is/are allowed.
- ☒ Claim(s) 48 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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Amendment of 4/18/03 has been entered. Claims 31-42, 44-51 and 53-56 are pending.

Claims 31-34 and 44-48 are under examination.

The following correction has been entered in the file record.

On form 326 mailed 1/21/03 (Paper 18), under "Disposition of claims", deleted all recitations of "55" and substituted therefore --56--. This change has been made in red ink and initialed and dated by the examiner.

The amendment of 4/18/03 has overcome 112 issues of record.

Prior art rejection are stated as follows:

Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sette et al in view of Matsuura et al and Sternberger.

Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rozzo et al in view of Matsuura et al and Sternberger.

Sette et al, Rozzo et al and Matsuura et al have been previously cited (Paper 18) for obviousness of providing a kit with antibodies; upon further consideration the examiner considers that provision of antigen "standards" also would have been obvious.

For example, to conduct the fluorescent staining required to conduct the flow cytometry assays of Sette et al, one would have wanted to conduct appropriate control tests to test for staining specificity. Sternberger teaches factors which give rise to nonspecific immunofluorescent staining, and he teaches that one of the appropriate control tests involves "blocking" (i.e. adsorption) of the antiserum/antibody directed against the cellular/tissue antigen to be stained with antigen. See particularly page 54,

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second and third paragraphs. One would have been motivated to provide antigen to perform this test.

Further, even if one were not motivated to conduct a blocking control for immunofluorescent or immunoprecipitation, one would have been motivated to provide antigen in a kit, since it is routine to test for the functional integrity of any antibody, after it has been shipped, or stored for a long time, in order to assure that the antibody used in any assays will provide reliable results.

Applicant's arguments with respect to claim 48 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Saunders whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday to Thursday from 8 AM to 5:30 PM. and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Art Unit: 1614

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Saunders/LR
July 18, 2003

David a Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1614